

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

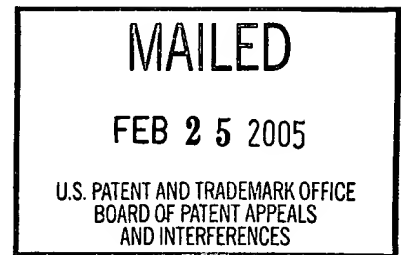
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CLAUDIO CAVAZZA

Appeal No. 2005-0027
Application No. 09/777,874

HEARD: January 13, 2005



Before MILLS, GRIMES, and GREEN, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 11-18 and 20-31, which are all of the claims pending in this application.

Claims 11 and 25-30 are illustrative of the claims on appeal and read as follows:

11. A composition comprising:
- (i) a first component selected from the group consisting of acetyl L-carnitine, a salt thereof and an ester thereof; and
 - (ii) a second component selected from the group consisting of hydroxycitric acid and a hydroxycitric acid derivative.

25. A method for facilitating the metabolism of lipids, comprising administering to a subject in need thereof, an effective amount of the composition of Claim 11.

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26. A method for reducing food consumption comprising administering to a subject in need thereof, an effective amount of the composition of Claim 11.

27. A method for reducing body weight comprising administering to a subject in need thereof, an effective amount of the composition of Claim 11.

28. A method for reducing serum triglycerides comprising administering to a subject in need thereof, an effective amount of the composition of Claim 11.

29. A method for treating hypertriglyceridaemia comprising administering to a subject in need thereof, an effective amount of the composition of Claim 11.

30. A method for treating hypercholesterolaemia comprising administering to a subject in need thereof, an effective amount of the composition of Claim 11.

The prior art references cited by the examiner are:

Wiegand	3,810,994	May 1974
Cavazza	4,268,524	May 1981
Stracher et al (Stracher)	5,008,288	April 1991
Burtle et al (Burtle)	5,030,657	July 1991
Moffett et al (Moffett)	5,536,516	July 1996
Hastings et al (Hastings)	5,626,849	May 1997

Wiener et al. (Weiner), "Liposomes as a Drug Delivery System," Drug Development and Industrial Pharmacy, Vol. 15, No. 10, pp. 1523-1556 (1989)

Grounds of Rejection

1. Claims 11-18, 20-27 and 31¹ stand rejected under 35 U.S.C. §103(a), as

¹ In the final rejection, page 4 (Paper No. 8) claims 11-18 and 20-31 were rejected over Hastings in view of Weigand or Burtle. In the Answer, the examiner removed the rejection from claims 28-30. Answer, page 2.

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obvious over Hastings in view of Wiegand or Burtle, by themselves or in combination.

2. Claims 11-18, 20-27 and 30-31 stand rejected under 35 U.S.C. §103(a), as obvious over Wiegand in view of Moffett.

3. Claim 18 stands rejected under 35 U.S.C. §103(a), as obvious over Hastings by itself or in view of Wiegand or Burtle, individually or in combination, further in view of applicant's statements in the prior art.

4. Claim 23 stands rejected under 35 U.S.C. §103(a), as obvious over Hastings by itself or in view of Wiegand or Burtle, individually or in combination, further in view of Weiner by itself or in combination with Stracher.

5. Claims 28-30 stand rejected under 35 U.S.C. §103(a), as obvious over Wiegand in view of Moffett or Hastings by itself or in view of Wiegand or Burtle individually or in combination, both as set forth above, further in view of Cavazza.

We affirm rejections 1 and 5 above. As our decision regarding rejections 1 and 5 disposes of all the claims on appeal, we do not reach the merits of rejections 2, 3, and 4 above. 37 C.F.R. § 40.50(a)(1).

Claim Grouping

According to appellant claims 11-18, 20-24 and 31 do not stand or fall together with method claims 25-30. Brief, page 5. In addition, claims 25-30 stand or fall individually and separately from composition claims and other method claims. Id. We select claim 11 as representative of claims 11-18, 20-24 and 31. We treat method

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claims 25-30 each individually. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

DISCUSSION

35 U.S.C. §103(a)

Claims 11-18, 20-27 and 31 stand rejected under 35 U.S.C. §103(a), as obvious over Hastings in view of Wiegand or Burtle, by themselves or in combination. Claims 28-30 stand rejected under 35 U.S.C. §103(a), as obvious over Wiegand in view of Moffett or Hastings by itself or in view of Wiegand or Burtle individually or in combination, both as set forth above, further in view of Cavazza.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). It is well-established that the conclusion that the claimed subject matter is prima facie obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

According to the examiner, "Hastings teaches dry formulations containing calcium salt of hydroxy citric acid, L-carnitine salt, Chromium, antioxidants and other components for weight loss. ... Hastings does not teach acetyl-carnitine." Answer, page 6. The examiner finds it would have been obvious to an artisan to use various forms of

carnitine from Hastings' teachings that "any other form of L-carnitine can be used (col. 3, lines 40-45) with the expectation of obtaining at least similar results since the active agent is carnitine." Id.

Hastings states that "L-carnitine also reduces fatigue, is used in the treatment of atherosclerotic heart diseases, advantageously increases HDL cholesterol while lowering LDL cholesterol, and decreases ketone levels in the blood." Col. 3, lines 60-65.

Wiegand describes a method and composition for treating obesity. Wiegand's compositions include L- and D-carnitine. Wiegand states that "derivatives of carnitine may be employed with the same effects." Col. 2, lines 29-30. Examples of derivatives described in Wiegand include acyl- and acetylcarnitine. Col. 2, lines 40-45.

According to the examiner, Burtle teaches compositions containing carnitine or esters of carnitine and pantothenic acid. Answer, page 7.

We find the examiner has presented sufficient evidence to support a prima facie case of obviousness. In particular Hastings teaches a weight loss composition including L-carnitine and hydroxycitric acid. Hastings suggests that other forms of carnitine may be used. Wiegand teaches a similar composition for the treatment of obesity which indicates that derivatives of L-carnitine, including acetyl carnitine, may be employed with the same effects. This explicit indication that acetyl carnitine may be substituted for L-carnitine in the art and employed with similar effects, provides an explicit reason, suggestion or motivation to combine the cited references.

Where the prior art, as here, gives reason or motivation to make the claimed invention, the burden then falls on an appellant to rebut that prima facie case. Such rebuttal or argument can consist of any other argument or presentation of evidence that is pertinent. In re Dillon, 919 F.2d 688, 692-93, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (en banc), cert. denied, 500 U.S. 904 (1991).

The appellant presents a Declaration under 37 CFR 1.132 of Franco Gaetani in rebuttal to the examiner's prima facie case. Appellant argues that Tables 2, 4 and 5 of the declaration provide evidence of the synergistic effects of the claimed combination of acetyl carnitine and hydroxycitric acid. Brief, page 7. Appellant argues that the “**embolded** results in each Table below [reproduced in part in the Brief, page 8] show the effects of the combination of acetyl L-carnitine and HCA are far greater than the effects of either compound alone.” Brief, pages 7-8. Appellant also argues that he has established the statistical significance of the results using the Student T-test. Brief, page 8.

The examiner responds, arguing that “the values for hydroxycitrate at 1g/100 g and 2 g/100 g diet in the table on page 3 of the Declaration are 46.6 +4.1 and 38.9 +3.8 respectively, compared to the control values of 62.8 + 3.5: the value for acetyl carnitine at 2 g/100 g diet 60.4 + 7.1 (this value is almost the same as the control): the combined value of hydroxycitrate and acetyl-carnitine as noted from this table is 31.6 +3.9. This value is the same as observed with hydroxycitrate taking into consideration the standard deviation. This value is not even additive.” Answer, page 5. The examiner

finds that “the scope of the claims is not commensurate with the amounts recited in the tables” of the Declaration and that “the examiner finds no unexpected or synergistic effect of the combination of acetyl-carnitine and hydroxycitric acid.” Answer, pages 5 and 6.

Upon review of the Declaration we find the examiner to be only partially correct with respect to his analysis of the data presented in the tables of the Declaration. First, both the examiner and appellant appear to have focused on the wrong data sets in the Declaration. The examiner and appellant have not reviewed the data with respect to the closest prior art. The closest prior art in the present case is not the results comparing hydroxycitrate and L-carnitine alone versus their combination, as highlighted by appellant in the Brief at page 8, and as discussed by the examiner in the Answer, page 5.

The closest prior art, is, rather, the combination described in Hastings of L-carnitine and hydroxycitric acid, as compared to acetylcarnitine and hydroxycitric acid, as claimed. Table 2 of the Declaration, for example, shows a comparison of a composition including L-carnitine and Garcinia cambogia (comprising hydroxycitrate) as compared to a composition including acetyl carnitine and hydroxycitrate. The final body weight increase was 38.6 ± 3.1 versus 36.8 ± 4.4 , an essentially similar result. Also present in the Declaration is a comparison of calcium hydroxycitrate and L-carnitine versus calcium hydroxycitrate and acetyl L-carnitine. These values are 28.7 ± 4.4 versus 31.6 ± 3.9 for body weight increase. Very similar results for these compounds

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also appear in Tables 4 and 5, comparing hypertriglyceridaemia and hypercholesterolemia reductions.

In view of the above, we do not find the appellant has put forth sufficient evidence to rebut the examiner's prima facie case of obviousness. The results set forth in the Declaration and discussed above, would reasonably appear to be expected results in view of the prior art. Expected beneficial results are evidence of obviousness just as unexpected beneficial results are evidence of unobviousness. See In re Skoner, 517 F.2d 947, 950, 186 USPQ 80, 82 (CCPA 1975). No synergistic result is shown in the Declaration evidence in view of the closest prior art.

The rejection of claim 11 over Hastings in view of Wiegand or Burtle is affirmed. Claims 12-18, 20-24 and 31 fall with claim 11.

Claims 25, 26 and 27

Claim 25 is directed to a method for facilitating the metabolism of lipids, comprising administering to a subject in need thereof, an effective amount of the composition of claim 11.

As set forth above, we have found the composition of claim 11 obvious in view of Hastings and Wiegand. Hastings describes at column 2, lines 14-28 that its composition helps burn fat stores and reduce the synthesis of fats. Hastings states that "L-carnitine also reduces fatigue, is used in the treatment of atherosclerotic heart diseases, advantageously increases HDL cholesterol while lowering LDL cholesterol,

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and decreases ketone levels in the blood.” Col. 3, lines 60-65. Hastings (abstract) also describes a method for inducing weight loss in a mammal by administering its L-carnitine and hydroxycitrate composition. Thus, the combination of Hastings and Wiegand reasonably appears to describe a method for facilitating the metabolism of lipids.

Claim 26 is directed to a method for reducing food consumption comprising administering to a subject in need thereof, an effective amount of the composition of claim 11. Hastings describes at column 2, lines 35-40 that its composition curbs appetite and reduces cravings. Thus, it would reasonably appear that the combination of Hastings and Wiegand describes a method for reducing food consumption by curbing appetite and reducing cravings.

Claim 27 is directed to a method for reducing body weight comprising administering to a subject in need thereof, an effective amount of the composition of claim 11. Hastings (abstract, column 1, lines 5-15) states that its described composition helps facilitate weight loss. Thus, the combination of Hastings and Wiegand would reasonably appear to describe a method of reducing body weight.

In view of the above, we affirm the rejection of claims 25-27 over Hastings in view of Wiegand or Burtle.

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Claims 28-30

Claims 28-30 stand rejected under 35 U.S.C. §103(a), as obvious over Wiegand in view of Moffett or Hastings by itself or in view of Wiegand or Burtle individually or in combination, both as set forth above, further in view of Cavazza.

Claim 28 is directed to a method for reducing serum triglyceride levels comprising administering to a subject in need thereof, an effective amount of the composition of claim 11. Claim 29 is directed to a method for treating hypertriglyceridaemia comprising administering to a subject in need thereof, an effective amount of the composition of claim 11. Hastings states that "L-carnitine also reduces fatigue, is used in the treatment of atherosclerotic heart diseases, advantageously increases HDL cholesterol while lowering LDL cholesterol, and decreases ketone levels in the blood." Col. 3, lines 60-65. As indicated above, Wiegand states that "derivatives of carnitine may be employed with the same effects." Col. 2, lines 29-30. Examples of derivatives described in Wiegand include acyl- and acetylcarnitine. Col. 2, lines 40-45.

Cavazza provides that "it has been found that a decrease in triglycerides and free fatty acids occurs upon the administration of acetylcarnitine." Column 2, lines 21-33. Cavazza proposes use of acetylcarnitine to effect "a reduction in total serum lipids and triglycerides." Column 2, lines 62-68. Thus, it would reasonably appear that the combination of Hastings and Wiegand inherently reduces triglyceride levels, as supported by Cavazza.

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Claim 30 is directed to a method for treating hypercholesterolaemia comprising, administering to a subject in need thereof, an effective amount of the composition of claim 11. As discussed above, Hastings clearly states that its composition is effective to lower LDL cholesterol. Thus, it would reasonably appear that the combination of Hastings and Wiegand describes a method for treating hypercholesterolaemia.

The rejection of claims 28-30 under 35 U.S.C. §103(a), as obvious over Wiegand in view of Moffett or Hastings by itself or in view of Wiegand or Burtle individually or in combination, both as set forth above, further in view of Cavazza, is affirmed.

CONCLUSION

The rejection of claims 11-18, 20-27 and 30-31 under 35 U.S.C. §103(a), as obvious over Hastings in view of Wiegand or Burtle, by themselves or in combination is affirmed. The rejection of claims 28-30 under 35 U.S.C. §103(a), as obvious over Wiegand in view of Moffett or Hastings by itself or in view of Wiegand or Burtle individually or in combination, both as set forth above, further in view of Cavazza, is affirmed. We do not reach the other rejections before us on the merits as our decision above, disposes of all the claims on appeal.

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No time period for taking any subsequent action in connection with this appeal
may be extended under 37 CFR § 1.136(a).

AFFIRMED


DEMETRA J. MILLS
Administrative Patent Judge


ERIC GRIMES
Administrative Patent Judge


LORA M. GREEN
Administrative Patent Judge

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